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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/913,351	08/13/2001	Aurora Brieva Delgado	B-4275PCT 618999-1	8629

7590 08/24/2004
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EXAMINER

KAM, CHIH MIN

ART UNIT PAPER NUMBER

1653

DATE MAILED: 08/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/913,351

Applicant(s)

DELGADO ET AL.

Examiner

Chih-Min Kam

Art Unit

1653

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 02 August 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
- ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: 1-10.

Claim(s) withdrawn from consideration: _____.

8. ☐ The drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____

Continuation of 2. NOTE: The amendment to the claims does not resolve the current issues under 35 USC 112, first and second paragraphs. In the amendment of August 2, 2004, claim 7 has been amended to be dependent from claim 3, although applicant indicates in the Remark section (last paragraph at page 7) that claim 3 has been amended to be dependent from claim 2, however, claim 3 has not been amended and is still dependent from claim 1. Applicants' response has been fully considered, however, claims 1-10 are rejected under 35 USC 112, first and second paragraphs.

If applicants' amendment were entered, it would have the following response:

1. Claims 1-10 are rejected under 35 USC 112, first paragraph, see paragraph 3 in the previous Office Action dated April 29, 2004. In response, applicants that claim 1 enables a person with ordinary skill in the art to make and use the invention without undue experimentation because the specification describes a method of formation of polysaccharide polypeptide conjugates, and the polysaccharide polypeptide conjugates can be within the 1/1 to 1/19 mol/mol range (page 19, lines 5-24). Further, the specification discloses in Examples 1-3 how to make the claimed product. This disclosure enables a person skilled in the art to make the claimed glycoconjugate without undue experimentation; Currently pending Claim 2 recites a mol/mol relation between the two polypeptides between 1/3 and 3/1; and Currently pending Claim 3 was amended to be dependent from currently pending Claim 2 (this is not indicated in the present claim 3; pages 6-8 of the response). The response has been considered, however, the argument is not found persuasive because the specification only demonstrates the make and use of a specific non-covalent complex of a polypeptide and a polysaccharide, where the polypeptide and the polysaccharide have defined structures and ratio in the complex, it does not disclose the identities of the claimed glycoconjugates which contain numerous variants of polypeptides and polysaccharides with undefined ratios, e.g., only 15 out of 230 amino acid residues in SEQ ID NO:1 are defined, nor demonstrates the effects of these various glycoconjugates. Thus, it requires undue experimentation to practice the claimed invention.

2. Claims 5 and 8 are rejected under 35 USC 112, second paragraph, as being indefinite because of the term "a higher production of tumor necrosis factor (TNF)". The term "a higher production of tumor necrosis factor (TNF)" renders the claim indefinite, it is unclear what reference point is used for comparison as to "higher production of TNF". In response, applicants provide a list of immunological diseases related to TNF, which are documented in the literature in Annex 1, and the reference points for "higher production of TNF" in Annex 2 (page 8 of the response). The response has been considered, regarding the diseases related to TNF, the argument is persuasive, the rejection is withdrawn. However, regarding the term "a higher production of tumor necrosis factor (TNF)", the argument is not fully persuasive because the limitation of this reference point is not cited in the claim, and without this reference point, it is not clear what "higher production of TNF" indicates.

Continuation of 5. does NOT place the application in condition for allowance because: The amendment to the claims does not resolve current issues under 35 USC 112, first and second paragraphs.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached at 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D. *CMK*
Patent Examiner

CMK
August 14, 2004

Jon P. Weber
Jon P. Weber, Ph.D.
Primary Examiner
Supervising